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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* CRAIG L. HOCUM, JAMES T. McCARTHY,  
DAVID P. STEENSMA, DAVID DINGLI, JAMES L. ROGERS, and  
EDWARD J. GALLAHER

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Appeal 2017-005738  
Application 13/519,843<sup>1</sup>  
Technology Center 1600

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Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and  
RYAN H. FLAX, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims 1–7 and 14 (Final Act.<sup>2</sup> 2).<sup>3</sup> Examiner entered a rejection under 35 U.S.C. § 101. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> Appellants identify the real party in interest as “Mayo Foundation for Medical Education and Research, of Rochester, MN” (Br. 3).

<sup>2</sup> Examiner’s October 28, 2015 Office Action.

<sup>3</sup> Pending claims 8-13 and 15 stand withdrawn from consideration (Final Act. 2).

## STATEMENT OF THE CASE

Appellants' "disclosure relates to modeling of biophysical parameters to determine pharmaceutical dosages" (Spec. ¶ 1). Appellants' claim 1 is representative and reproduced below:

1. A system, comprising:
  - a biophysical simulation engine that represents a process by which red blood cells are produced in humans, wherein the biophysical simulation engine includes a plurality of parameters the values of which are patient-specific; and
  - a processing unit configured to execute the biophysical simulation engine, wherein the processing unit:
    - receives patient-specific historical hemoglobin (Hgb) data and corresponding historical erythropoietic stimulating agent (ESA) dosage data,
    - models a patient-specific response to the historical ESA dosage data for a plurality of sets of parameter values,
    - selects at least one set of the parameter values such that the modeled patient response to the historical ESA dosage data substantially fits the patient-specific historical Hgb data,
    - simulates patient-specific Hgb values that would be obtained by the patient over a predetermined period of time based on the biophysical simulation engine, the at least one selected set of parameter values, and a plurality of proposed therapeutic ESA dosages, and
    - identifies at least one of the plurality of proposed therapeutic ESA dosages that substantially maintains the simulated patient-specific Hgb values within a target range during the predetermined period of time;
  - wherein the plurality of parameters includes an erythropoietin setup rate parameter having a patient-specific value that when applied to the model raises the simulated patient specific hemoglobin values to a level equal to the patient-specific historical Hgb data on a first day for which the simulation is performed, and
  - wherein the biophysical simulation engine takes into account delay in increase of simulated patient-specific Hgb values in response to delivery of the proposed therapeutic ESA

dosages and delay in decrease of simulated patient-specific Hgb values due to lifespan of circulating red blood cells in the patient.

(Br. 2)

The claims stand rejected as follows:

Claims 1–7 and 14 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter.

#### ISSUE

Does the evidence of record support Examiner's finding that Appellants' claimed invention is directed to non-statutory subject matter?

#### FACTUAL FINDINGS

FF 1. Appellants disclose:

In [End Stage Renal Disease (ESRD)] patients, as well as in other patient populations experiencing reduced hemoglobin levels, the biophysical system that regulates erythropoietin production does not function properly. [Erythropoietic Stimulating Agents (ESAs)] are often prescribed to manage hemoglobin levels (anemia) in ESRD patients and in other patient populations. An ESA prescription may include, for example, intravenous injection of darbepoetin alfa (Aranesp®) or Recombinant Human Erythropoietin (rHuEPO). The current protocol for developing ESA prescriptions produces patterns of hemoglobin (Hgb) oscillation that subject patients to a cycle of overshoot and undershoot of target Hgb values. For example, when the patient exhibits a low Hgb, the dosage may be dramatically increased in an attempt to quickly raise Hgb levels. When the patient exhibits a high Hgb, interruption of ESA therapy (by greatly reducing the dose or withholding administration) may lead to under-dosing of the ESA, which, in turn, leads to an undershoot of Hgb values. The result is an undesirable fluctuation of Hgb levels above and below the target range. The period of the High-Low-High may take up to nine months for a complete cycle. Hgb values are often

measured monthly, rendering Hgb cycling practically imperceptible.

(Spec. ¶ 6; *see id.* ¶ 3.)

FF 2. Appellants disclose that their

system includes a patient-specific biophysical simulation model that, based on a patient's historical response to ESA therapies, determine a target dosing level which can be translated to a dosing regimen titrated to available commercial doses. The dosing regimen thus obtained can be configured to simultaneously achieve and sustain adequate and stable Hgb values for extended periods of time as well as minimize or eliminate Hgb oscillations (commonly known as Hgb cycling). The total amount (and cost) of ESA administered may also be reduced or minimized. If the patient's overall medical condition remains stable, Hgb values have been shown, using the techniques described herein, to remain stable at a given target level. If the patient's underlying medical condition changes, the system includes a diagnostic system which can be used to establish a new target dosing level that may restore Hgb values to a desired target level in a minimum of time.

(Spec. ¶ 53.)

FF 3. Appellants disclose:

Due to its longer half[-]life, darbepoetin alfa requires approximately five days for complete elimination from the serum, and has a prolonged period of pharmacological activity. This allows providers to administer the drug less frequently. But the extended half-life of darbepoetin alfa, in combination with red blood cell dynamics, creates a physiological consequence. After an administration of darbepoetin alfa, [red blood cell (RBC)] production is enhanced for up to 26 days. This delay, if not factored into the design of the prescription, sets up Hgb cycling. It is not uncommon for patients to experience 12-18 months of Hgb “overshoot” and “undershoot” as providers try to establish an adequate and stable Hgb level following existing protocols. The system accounts for feedback and delay in the erythropoietic process by establishing a target

dosing level, assisting with the design of a dosing regimen, and monitoring results over time.

(Spec. ¶ 64; *see id.* ¶ 2.)

#### ANALYSIS

The system of Appellants' claim 1 comprises: (1) a biophysical simulation engine that represents a process by which red blood cells are produced in humans that includes a plurality of patient-specific parameter values and (2) a processing unit configured to execute the biophysical simulation engine (Br. 2).

The biophysical simulation engine of Appellants' system: (a) takes into account delay in increase of simulated patient-specific Hgb values in response to delivery of the proposed therapeutic ESA dosages and delay in decrease of simulated patient-specific Hgb values due to lifespan of circulating red blood cells in the patient and (b) includes an erythropoietin setup rate parameter, among the plurality of parameters, that has a patient-specific value that when applied to the model raises the simulated patient-specific hemoglobin values to a level equal to the patient-specific historical Hgb data on a first day for which the simulation is performed (*id.*).

The processing unit of Appellants' system: (i) models a patient-specific response to historical ESA dosage data for a plurality of sets of parameter values; (ii) selects at least one set of parameter values such that the modeled patient response to the historical ESA dosage data substantially fits the patient-specific historical Hgb data; (iii) simulates patient-specific Hgb values that would be obtained by the patient over a predetermined period of time based on the biophysical simulation engine, the at least one selected set of parameter values, and a plurality of proposed therapeutic ESA dosages; and (iv) identifies at least one of the plurality of proposed

therapeutic ESA dosages that substantially maintains the simulated patient-specific Hgb values within a target range during the predetermined period of time (*id.*).

*Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) sets forth the following two-step analysis for determining patent eligibility under Section 101:

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts [e.g., a law of nature, natural phenomenon, or abstract idea]. If so, we then ask, what else is there in the claims before us? . . . We have described step two of this analysis as a search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.

*Id.* (alterations, citations, and quotation marks omitted).

With respect to *Alice*'s first step, Examiner finds that, when considered as a whole, Appellants' claimed system "simply describes the concept of gathering and combining data by reciting steps of organizing information through mathematical relationships to generate additional information" (Final Act. 3). Thus, Examiner finds that the system of Appellants' claim 1 is directed to non-statutory subject matter, specifically, an abstract idea (Final Act. 3; *see also id.* at 3–5; Ans. 2).

With respect to *Alice*'s second step, the search for an inventive concept, Examiner finds that the "processing unit" of Appellants' claim 1, represents "generic hardware that nearly every computer will include" and a series of processing steps (Final Act. 4). With respect to the hardware, Examiner finds that "[n]one of the hardware offers a meaningful limitation beyond generally linking the system to a particular technological environment, that is, implementation via computers" (Final Act. 4). With

respect to the processing steps, Examiner finds that these steps represent nothing more than data gathering and manipulation steps (Final Act. 4).

Taken together, Examiner finds that “mere data gathering in conjunction with an abstract idea is not enough to qualify as ‘significantly more’” and Appellants’ claimed system does “not recite inventive steps outside of data manipulation[] or [steps that] improve[] . . . the functioning of the computer itself” (Final Act. 4; *see* Ans. 2 (“Other than manipulation of data, there is no evidence for an improvements to another technology or to the functioning of the computer itself, or for applying the judicial exception with, or by use of, a particular machine”)). Therefore, Examiner finds that, when “[v]iewed as a whole, th[e] additional claim elements do not provide meaningful limitations to transform the abstract idea into a patent eligible application of the abstract idea such that the claims amount to significantly more than the abstract idea itself” (Final Act. 4).

We find no error in Examiner’s finding that Appellants’ claim 1 is directed to non-statutory subject matter.

Appellants contend that the selection, simulation and identification steps performed by the processing unit “are not conventional steps that those in the field would have routinely practiced, in that application of the recited claim limitations was not widely prevalent at the time the application was filed” (Br. 8). In this regard, Appellants contend that “[t]hese claim limitations are significant because the resulting invention solves the Hgb cycling problem by ‘identif[ying] at least one of the plurality of proposed therapeutic ESA dosages that substantially maintains the simulated patient-specific Hgb values within a target range during the predetermined period of time’” and, thereby, “[t]he dosing regimen thus obtained can be configured

to simultaneously achieve and sustain adequate and stable Hgb values for extended periods of time as well as minimize or eliminate Hgb oscillations (commonly known as Hgb cycling)” (Br. 9 (citing Spec. ¶¶ 6 and 53) (alteration original)).

Appellants further contend that accounting for “delay in increase of simulated patient-specific Hbg values in response to delivery of the proposed therapeutic ESA dosages and delay in decrease of simulated patient-specific Hgb values due to lifespan of circulating red blood cells in the patient,” as is required by the system of Appellants’ claim 1, “furtheres the goal of the claimed invention to ‘identif[y] at least one of the plurality of proposed therapeutic ESA dosages that substantially maintains the simulated patient-specific Hgb values within a target range during the predetermined period of time’” (Br. 9–10 (citing Spec. ¶ 64) (alteration original)).

Therefore, Appellants contend that the system set forth in their claim 1 provides “additional elements” that “go[] beyond merely ‘processing information, converting one form of numerical representation into another, and correlating information’ and, thus, represent “more than mere [well-understood, routine, or conventional techniques in the field, or] instructions to ‘apply’ the so-called abstract idea” (Br. 10; *see id.* at 10–11).

We are not persuaded.

Instead, we agree with Examiner’s finding that Appellants’ claimed invention, which is performed on a generic computer, does no more than collect and manipulate data to generate additional information. “[S]imply implementing a mathematical principle on a physical machine, namely a computer, [is] not a patentable application of that principle.” *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289,

1301 (2012). Further, “an invention directed to collection, manipulation, and display of data [is] an abstract process.” *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 850 F.3d 1332, 1340 (Fed. Cir. 2017); *see generally id.* at 1340-41.

Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible. “If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.” *Parker v. Flook*, 437 U.S. 584, 595[] (1978) (internal quotations omitted).

*Digitech Image Techs., LLC v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014). *See also Fair Warning Ip, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089, 1093 (Fed. Cir. 2016) (“analyzing information by steps people go through in their minds, or by mathematical algorithms, without more,” are “essentially mental processes within the abstract-idea category”); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1146 (Fed. Cir. 2016) (“Methods which can be performed entirely in the human mind are unpatentable . . . because [they] embody the ‘basic tools of scientific and technological work’ that are free to all men and reserved exclusively to none”). *Cf.* FF 1. Thus, when the elements of Appellants’ claim 1 are considered as a whole, the claim elements fail to add enough to “‘transform the nature of the claim’ into a patent-eligible application.” *Intellectual Ventures*, 850 F.3d at 1338; *see id.* at 1341-1342. *See also CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) (“The mere manipulation or reorganization of data . . . does not satisfy the transformation prong”).

### CONCLUSION OF LAW

The evidence of record fails to support Examiner's finding that Appellants' claimed invention is directed to patent ineligible subject matter. The rejection of claim 1 under 35 U.S.C. § 101 as directed to non-statutory subject matter is affirmed. Claims 2–7 and 14 are not separately argued and fall with claim 1.

### TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED